

REMARKS

This is a full and timely response to the outstanding FINAL Office Action mailed August 2, 2006. The Examiner is thanked for the thorough examination of the present application. Upon entry of this response, claims 1 and 3-20 are pending in the present application. Claim 5 is objected to because of an informality. Claims 1, 3-11 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Moore*, III et al (U.S. Pat. No. 6,402,757, hereinafter "*Moore*"), in view of *Siddiqui* (U.S. Pat. No. 5,897,319), further in view of *Wagner* et al. (U.S. Pat. No. 5,897,319, hereinafter "*Wagner*"), further in view of *Morse* (U.S. Pat. No. 38,119). Applicants have amended claims 2 and 13 only to correct minor typographical errors.

Applicants respectfully request consideration of the following remarks contained herein. Reconsideration and allowance of the application and presently pending claims are respectfully requested.

I. The Office Action Does Not Address Each and Every Claim

Applicants appreciate the thorough examination provided for claims 1, 3-11. However, while the current FINAL Office Action indicates that claims 12-20 are pending in the summary portion, the remainder of the Office Action does not address these claims. (See Office Action, pg. 2-5.)

Applicants respectfully submit that "each pending claim should be mentioned by number and its treatment or status be given" (MPEP §707.07(i)). As the FINAL Office Action does not address claims 12-20, Applicants respectfully submit that the finality of the current Office Action should be withdrawn.

II. Response to Claim Objection

The Office Action states that “*claim 5 is objected to because of the following informalities: “grooves varies” is incorrect usage.*” (Office Action, pg. 2) However, claim 5 was amended to overcome this rejection in the response to the prior Office Action (mailed 11/15/05). Applicants respectfully request that this objection be withdrawn in light of the correction made.

III. Response to Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3-11 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Moore*, in view of *Siddiqui*, further in view of *Wagner*, further in view of *Morse*. For at least the reasons set forth below, Applicants traverse these rejections.

Independent Claim 1 is Patentable Over Moore, in view of Siddiqui, further in view of Wagner, further in view of Morse

Applicants respectfully submit that independent claim 1 patentably defines over the combination of *Moore*, *Siddiqui*, *Wagner* and *Morse* for at least the reason that the combination fails to disclose, teach or suggest certain features in claim 1.

Claim 1 recites:

1. An osteosynthesis and compression screw for coaptation of small bone fragments, the screw being formed by a single longitudinal body having a longitudinal axis, and comprising:

- a proximal portion formed by a screw head provided with an outside thread, said proximal portion being of diameter greater than the diameter of the remainder of the screw;
- an intermediate portion having no thread; and
- a distal portion provided with an outside thread;

wherein:

- each of the screw head and the distal portion includes **at least one helical groove, firstly extending over the entire axial length of its thread,**

and secondly being formed through each thread in such a manner to form tapping means; and

· the terminal zone of the distal portion is provided with preparation means for preparing a housing in the bone fragments for receiving the intermediate and distal portions of the screw.

(*Emphasis added.*) First, Applicants agree with the Office Action that “*Moore and Siddiqui fail to disclose that the grooves are helical.*” (Office Action, pg. 3) The Office Action apparently relies on the *Wagner* and *Morse* references to teach the feature of a “helical groove” as recited in claim 1 above. Applicants respectfully disagree with the Office Action’s assertion and submit that neither the *Wagner* reference nor the *Morse* reference teach the helical groove feature recited in claim 1 above. Specifically, neither *Wagner* or *Morse* teach the feature, “at least one helical groove, firstly extending over the entire axial length of its thread, and secondly being formed through each thread in such a manner to form tapping means.” While the *Wagner* reference relates to a self-tapping implant with helical flutes, it is clear from the figures (see, e.g., FIGS. 1 and 2) that the “helical flutes” taught by *Wagner* do not extend over the entire axial length of its thread.

Regarding the *Morse* reference, Applicants point out that *Morse* relates to an improvement in drill bits, namely a “twist drill,” while the present disclosure relates to an osteosynthesis and compression screw for coaptation of small bone fragments. Nevertheless, the Applicants submit that the *Morse* reference does not teach the feature emphasized in claim 1 above. That is, *Morse* does not teach a “helical groove, . . . , and secondly being formed through each thread in such a manner to form tapping means.” As seen in FIG. 1 of the present disclosure, the groove (10) is formed through each thread (4), (7). Applicants submit that *Morse* does not teach this feature where

the helical groove is "formed through each thread" as recited in claim 1 above. (See, e.g., FIG. 1 and related text on the "twist drill" in the *Morse* reference.)

Accordingly, Applicants respectfully submit that independent claim 1 patently defines over *Moore*, *Siddiqui*, *Wagner* and *Morse* for at least the reason that the combination fails to disclose, teach or suggest the features emphasized in claim 1 above.

Dependent Claims 3-11 are Patentable Over Moore, in view of Siddiqui, further in view of Wagner, further in view of Morse

Because independent claim 1 patently defines over the combination of *Moore*, *Siddiqui*, *Wagner* and *Morse*, dependent claims 3-11 are allowable over the combination as a matter of law for at least the reason that these claims contain all the features and elements of their corresponding independent claim. See, e.g., *In re Fine*, 837 F. 2d 1071 (Fed. Cir. 1988).

Additional Remarks

As a separate and independent basis for the patentability of claims 1, 3-20, Applicants respectfully traverse the rejections as failing to identify a proper basis for combining the cited references. In combining these references, the Office Action states only that the combination would have been obvious "*to one of ordinary skill in the art at the time the invention was made to make the Moore grooves helical to increase the amount of space to receive the cut material and avoid clogging.*" (Office Action, pg. 3) Without providing further support, the Office Action combines the four references and alleges that the combination teaches the features recited in each of the claims.

Applicants submit that the present invention relates to a compression screw for coaptation of small bone fragments. Such a screw, because of the compression it generates, is reciprocally subjected to significant mechanical stresses. Therefore, the screw must be designed to assert a significant amount of mechanical resistance. Furthermore, a sufficient amount of mechanical resistance is difficult to maintain since the screw is necessarily small in size. The screw is specifically intended for the coaptation of small bone fragments. One important aspect of the present invention is that the screw is intended to be screwed directly into the bone without the need for pre-drilling. The screw includes preparation means and grooves that respectively provide self-drilling and self-tapping functions. This implies that the screw is subjected to significant mechanical stresses from the self-drilling and self-tapping performed with the tapping grooves and preparation means during its placement into bone fragments.

Also, it is important that the preparation means and the tapping means be very efficient, in order to allow a "clean" (*i.e.*, no bone damage) and accurate penetration of the screw into the bone, especially since the screw is intended to be inserted into small bone fragments. In other words, a self-drilling and self-tapping screw must be very "aggressive" in order to be screwed into bones by a surgeon. The efficiency of the tapping grooves is directly dependant on the length of the groove. That is, the longer the grooves, the more effective the self-tapping effect.

However, the grooves also introduce weak zones due to the removal of material from the screw body. The longer the grooves, the weaker the screw. Thus, compression screws for small bone fragments in the prior art do not teach of grooves that extend over the entire axial length of the thread but only over a fraction of the axial

length. However, such a design implies that the screw is less "aggressive." Therefore, a pilot hole, even of small diameter, may be necessary. Hence, there was a need for the following: (i) a compression screw, (ii) for coaptation of small bone fragments, (iii) with excellent self-tapping properties, (iv) and also with an excellent mechanical resistance. In other words, the technical problem the invention addresses is the need for a compression screw with a high level of aggressiveness with good mechanical resistance. The invention addresses this need by providing a compression screw with helical grooves for coaptation of small bone fragments.

Such a helical design allows the zones of weakness resulting from the removal of material to be distributed around the longitudinal axis of the screw. Therefore, it is possible to have long grooves (*i.e.*, extending over substantially the entire length of the thread) without substantially weakening the screw. In other words, because of the helical shape of the grooves, the invention provides an excellent compromise between self-tapping properties and the mechanical resistance.

Applicants submit that the *Moore*, *Siddiqui*, *Wagner* and *Morse* references are not similar enough to be picked apart in a piecemeal fashion. While *Moore* and *Siddiqui* relate to fastening and compression of fractured bones, *Wagner* relates to dental implants and *Morse* relates to an improvement in drill bits. Applicants note that the Office Action relies on no less than four different references from unrelated technical fields (*i.e.*, compression bone screws, dental implants and even drill bits) to teach the features recited in the claims. In the present case, it appears that the Office Action fails to appreciate the technical relationships that exist between the claimed technical features as well as the true technical problem involved. This apparently led to

the piecemeal combination of technical features arbitrarily selected from various documents from different fields. These features were apparently selected not on the basis of objective reasoning but on the basis of foreknowledge of the invention. Such an "*a posterior*" approach should be avoided as it necessarily leads to a distorted evaluation of the invention.

Regarding the *Siddiqui* reference, Applicants fail to understand how a person skilled in the art (facing the present problem concerning compression screws) would consider *Moore's* screw as the most promising starting point and then consider the teachings of *Siddiqui* to transform *Moore's* screw into a compression screw. Such an approach is illogical and is clearly an ex post facto approach. Applicants submit that one skilled in the art would not consider the teachings of *Moore* regarding the length of the groove to modify *Siddiqui's* screw since *Moore's* screw is not a compression screw. Furthermore, one skilled in the art would know that long tapping grooves (that extend substantially the entire axial length of the thread) are likely to weaken the screw. Thus, one skilled in the art would not apply the teaching of *Moore* to increase the length of grooves taught by *Siddiqui*. In addition, even if one skilled in the art would consider the *Moore* reference as the most promising starting point, it would be illogical for one skilled in the art to modify *Moore's* screw based on only part of the teachings of *Siddiqui*. In other words, Applicants believe that one skilled in the art would have made the distal grooves of *Moore* as short as those of *Siddiqui*.

Regarding the *Wagner* and *Morse* references, the teaching of *Wagner* is not relevant to the present invention as *Wagner* discloses a dental implant (and not an osteosynthesis screw), which does not generate any type of compression effect.

Furthermore, *Wagner* does not teach or even suggest why helical grooves would be technically advantageous. The teaching of the *Morse* reference is also not relevant to the present invention. The *Morse* reference only teaches that a specific arrangement of spiral grooves (*i.e.*, a groove with increasing twist) within a twist drill is likely to increase the amount of space to receive material and avoid clogging. Increasing the amount of space to receive material and avoid clogging is relevant to drilling applications but is not relevant to the technical problem involved in the present case.


It is well-settled law that in order to properly support an obviousness rejection under 35 U.S.C. § 103, there must have been some teaching (either express or implied) in the prior art to suggest to one skilled in the art that the claimed invention would have been obvious. W. L. Gore & Associates, Inc. v. Garlock Thomas, Inc., 721 F.2d 1540, 1551 (Fed. Cir. 1983). When an obviousness determination is based on multiple prior art references, there must be a showing of some “teaching, suggestion, or reason” to combine the references. Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997) (also noting that the “absence of such a suggestion to combine is dispositive in an obviousness determination”).

If there was no motivation or suggestion to combine selective teachings from multiple prior art references, one of ordinary skill in the art would not have viewed the present invention as obvious. See In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); Gambro Lundia AB, 110 F.3d at 1579, 42 USPQ2d at 1383 (“The absence of such a suggestion to combine is dispositive in an obviousness determination.”). For at least this additional and independent basis, the rejections are misplaced and should be withdrawn.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,


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